

Civil Action Number	Bruce Rosenzweig, M.D. Docket # 2817 Exhibit A
2:12-cv-02027	Gullett et al v. Johnson & Johnson et al
2:12-cv-02134	Elaine Anderson v. Johnson & Johnson, Inc. et al
2:12-cv-02191	Angelia M. & Manuel M. Ramirez v. Johnson & Johnson, et al.
2:12-cv-02192	Mary Frances & Joseph L. Richard v. Johnson & Johnson, et al.
2:12-cv-02193	Dawn & David Sequino v. Johnson & Johnson, et al.
2:12-cv-02198	Mary & Jeffrey Ward v. Johnson & Johnson, et al.
2:12-cv-02199	Leslie Warner v. Johnson & Johnson, et al.
2:12-cv-02200	Judy Haddon v. Johnson & Johnson, et al.
2:12-cv-02251	Kathy & Joseph Birt v. Ethicon, et al
2:12-cv-02257	Patricia & Martin, Jr. Kuks v. Ethicon, et al
2:12-cv-02264	Charlotte A. & Troy Day v. Ethicon, et al
2:12-cv-02283	Linda G. Braden & Greg Combs v. Johnson & Johnson, et al.
2:12-cv-02315	Karen Conley v. Ethicon, et al
2:12-cv-02316	Helen Harper v. Ethicon, et al
2:12-cv-02374	Helen Van Wyck Johnson & Johnson, et al.
2:12-cv-02412	Bonnie & Calvin Huggins v. Ethicon, et al
2:12-cv-02414	Norma & Larry Carroll v. Johnson & Johnson, et al.
2:12-cv-02424	Kimberly Stevens v. Johnson & Johnson, et al.
2:12-cv-02446	Cynthia & Raymond, Sr. Falcon v. Ethicon, et al
2:12-cv-02448	Melissa Mincey v. Ethicon, et al
2:12-cv-02478	Donna & Earl Matthews v. Johnson & Johnson, et al.
2:12-cv-02485	Donna Murphy v. Johnson & Johnson, et al.
2:12-cv-02489	Joanne Phillips v. Johnson & Johnson, et al.
2:12-cv-02512	Linda Madding v. Ethicon, et al
2:12-cv-02532	Rhonda Cooper v. Ethicon, et al

Civil Action Number	Case
2:12-cv-02565	Patsy & Howard Mays v. Johnson & Johnson, et al
2:12-cv-02581	Anita Fisher v. Johnson & Johnson, et al
2:12-cv-02584	Trina Hill v. Ethicon, et al
2:12-cv-02633	Kandy P. & Rick Dotson v. Johnson & Johnson, et al
2:12-cv-02634	Ila Cosgray v. Johnson & Johnson, et al
2:12-cv-02642	Tabitha Williamson v. Johnson & Johnson, et al
2:12-cv-02657	Lori & Duane Morse v. Johnson & Johnson, et al
2:12-cv-02662	Joyce & William Thomas v. Johnson & Johnson, et al
2:12-cv-02663	Debbie & Charles Tomlinson v. Johnson & Johnson, et al
2:12-cv-02672	Deborah & Steven Ray, Jr. Young v. Johnson & Johnson, et al
2:12-cv-02687	Kathleen & Glennon Toennies v. Ethicon, et al
2:12-cv-02688	Victoria Soltanshahi v. Ethicon, et al
2:12-cv-02689	Karen A. & Thomas F. Lyszczarz v. Ethicon, et al
2:12-cv-02690	Barbara Lawyer-Johnson v. Ethicon, et al
2:12-cv-02716	Brenda Simpson v. Johnson & Johnson, et al
2:12-cv-02741	Sara & Terrance Bell v. Ethicon, et al
2:12-cv-02742	Jennifer & Hilario Aguilar v. Ethicon, et al
2:12-cv-02797	Susan & Hubert Jones (SUSAN JONES IS DECEASED) v. Ethicon, et al
2:12-cv-02799	Susan Clones v. Ethicon, et al
2:12-cv-02802	Kathy Robertson v. Ethicon, et al
2:12-cv-02805	Donna & Joe Moosman v. Ethicon, et al
2:12-cv-02829	Kimberly Hill v. Ethicon, et al
2:12-cv-02865	Mattie J. Brooks v. Johnson & Johnson, et al
2:12-cv-02879	Lisa A. Russell v. Ethicon, et al
2:12-cv-02921	Susan D. Bartley v. Ethicon, et al
2:12-cv-02934	Dawn Corda-Cullipher v. Johnson & Johnson, et al
2:12-cv-02943	Kathy Blake v. Johnson & Johnson, et al
2:12-cv-02951	Brenda J. & Barry Wooden v. Johnson & Johnson, et al

Civil Action Number	Case
2:12-cv-02955	Anne M. Currie v. Johnson & Johnson, et al
2:12-cv-02956	Audrey & Theron Smallridge v. Johnson & Johnson, et al
2:12-cv-02959	Jamie & Steven Rutherford v. Ethicon, et al
2:12-cv-02971	Janice & Don Fields v. Johnson & Johnson, et al
2:12-cv-02975	Grethel Taylor v. Johnson & Johnson, et al
2:12-cv-02989	Shannon L. Smith v. Ethicon, et al
2:12-cv-02991	Susan & Simon Thomas Grizzle v. Ethicon, et al
2:12-cv-02994	Vicki & Randall Trammell v. Ethicon, et al
2:12-cv-02999	Mary Allmon v. Ethicon, et al
2:12-cv-03013	Deborah & Robert Kissel v. Johnson & Johnson, et al
2:12-cv-03074	April & Danny Berry v. Ethicon, et al
2:12-cv-03076	Stephanie & Davin Booher v. Ethicon, et al
2:12-cv-03078	Araceli Baez v. Ethicon, et al
2:12-cv-03085	Mary Diana Book v. Ethicon, et al
2:12-cv-03091	Shirlene Franklin v. Ethicon, et al
2:12-cv-03097	Deborah & Tony Mattingly v. Ethicon, et al
2:12-cv-03108	Melissa Moore v. Ethicon, et al
2:12-cv-03118	Carol Noffsinger v. Johnson & Johnson, et al
2:12-cv-03119	Glenna T. Hensley v. Ethicon, et al
2:12-cv-03122	Kimberly & Glen A. Martello v. Ethicon, et al
2:12-cv-03123	Tammy Webb-Henson v. Ethicon, et al
2:12-cv-03124	Katherine & Henry, II Smallwood v. Ethicon, et al
2:12-cv-03129	Kelly L. & John D. White v. Ethicon, et al
2:12-cv-03131	Sara Camille Jones v. Ethicon, et al
2:12-cv-03136	Christine & Joseph Webb v. Ethicon, et al
2:12-cv-03145	Tracy & Kevin Woosley v. Johnson & Johnson, et al
2:12-cv-03162	Joann S. Bradley v. Ethicon, et al
2:12-cv-03163	Geralddean Gaylor v. Johnson & Johnson, et al
2:12-cv-03166	Christine Walker v. Ethicon, et al

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Bruce Rosenzweig, M.D.)

Pending before the court is the Motion to Exclude Certain Opinions of Bruce Rosenzweig, M.D. [ECF No. 2047] filed by the defendants Ethicon, Inc. and Johnson & Johnson (collectively “Ethicon”). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.¹

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*’s core considerations for assessing expert

¹ Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2047-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Rosenzweig is a pelvic surgeon and urogynecologist. Ethicon seeks exclusion of his expert testimony on several grounds.

a. Alternative Design

First, Ethicon argues that Dr. Rosenzweig should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Ethicon does not challenge Dr. Rosenzweig's qualifications or the reliability of this expert testimony; instead, Ethicon challenges the relevance of this expert testimony. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I **RESERVE** ruling until trial.

Next, Ethicon claims Dr. Rosenzweig is not qualified to offer expert testimony on whether there are clinical differences between mechanical-cut and laser-cut mesh products. According to Ethicon, Dr. Rosenzweig cannot offer expert testimony on this issue because he is not specially trained in product design processes. However, I find that a urogynecologist who has extensive experience working with mechanical-cut and laser-cut mesh products—like Dr. Rosenzweig—is qualified to offer expert testimony of this sort. The plaintiffs' Motion is **DENIED** on this point.

Third, Ethicon challenges the reliability of Dr. Rosenzweig's expert testimony about mechanical-cut and laser-cut mesh. Faced with this challenge, the plaintiffs retort that Dr. Rosenzweig's clinical experience provides a reliable foundation for this expert testimony.

In the abstract, experience—on its own or accompanied by little else—is a reliable basis for expert testimony. *See Kumho*, 526 U.S. at 156. But the reliability inquiry must probe into the relationship between the experience and the expert testimony:

If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.

Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Here, the court does not have enough information to judge the reliability or relevance of Dr. Rosenzweig's particular experience.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on whether mechanical-cut mesh is safer than laser-cut mesh based primarily on an expert's clinical experiences. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

Finally, Ethicon challenges the reliability of Dr. Rosenzweig's expert testimony about Ultrapro mesh as an alternative. Ethicon first argues that this testimony is based on a logical fallacy—the logical fallacy being that a device that results in fewer complications is a safer alternative design. I see no logical fallacy here; whether an alternative device has few complications is surely related to whether the alternative is safer. Ethicon then argues that Dr. Rosenzweig cannot claim Ethicon had insufficient long-term studies about its mesh products and then offer up an alternative (i.e., Ultrapro) that was the subject of a single study and that Dr. Rosenzweig believes should be studied longer. I am not convinced these facts render Dr. Rosenzweig's expert testimony unreliable, especially considering his reliance on other studies that he explains are relevant to this expert testimony. While Ethicon may explore its concerns on cross-examination,

its Motion is **DENIED** on this point.

b. Warnings

Ethicon asks the court to exclude Dr. Rosenzweig’s expert testimony about whether the relevant Instructions for Use adequately warned about the duration, severity, and frequency of risks. Ethicon does not claim Dr. Rosenzweig is unqualified or offers expert testimony that is unreliable.² It appears Ethicon’s argument centers on the relevance of this expert testimony. In Ethicon’s opinion, a manufacturer does not have a legal obligation to warn about the duration, severity, and frequency of risks, so these matters do not bear on whether Ethicon provided adequate warnings. I disagree; as do other courts. *E.g.*, *Cisson v. C. R. Bard Inc.*, No. 2:11-cv-195, 2013 WL 5700513, at *7 (joining other courts in finding “a failure to warn about the rate or severity of potential injury creates a jury question over the adequacy of warnings.”). Accordingly, Ethicon’s Motion is **DENIED** on this point.

c. Properties

Ethicon seeks to preclude Dr. Rosenzweig from testifying about degradation and other biomaterials opinions—specifically his opinions that Ethicon’s mesh devices degrade, are subject to fraying and particle loss, and are cytotoxic. Ethicon objects to Dr. Rosenzweig’s testimony on these subjects because he cannot connect the alleged phenomena to “adverse events experienced by women.” Mem. 12–13 [ECF No. 2049]. I reject this argument. A single expert need not provide all the pieces of

² In its reply brief—and in the briefest fashion—Ethicon claims Dr. Rosenzweig is not qualified to offer this expert testimony. I decline to decide a matter raised in such short order, especially when raised in a reply brief and without affording the plaintiffs an opportunity to respond.

the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710 (S.D. W. Va. 2014) (rejecting a similar argument). Dr. Rosenzweig’s testimony is a relevant step towards establishing general causation. Nor does his alleged inability to connect degradation, fraying, particle loss, and cytotoxicity to specific complications undermine the reliability of his testimony that these phenomena occur. Ethicon’s Motion is **DENIED** on these matters.

d. MSDS

Ethicon seeks to preclude Dr. Rosenzweig from using the MSDS—specifically the MSDS statement that polypropylene is incompatible with strong oxidizers—as the basis for his opinion that the mesh at issue should not be used in the vagina.

First, Ethicon argues that the MSDS “provides no support for the opinions expressed,” because the MSDS “does *not* forbid implantation in humans.” Mem. 14 [ECF No. 2049] Additionally, Ethicon states that the MSDS is for “‘polypropylene resin,’ not polypropylene and certainly not Prolene.” *Id.* I find these concerns without merit. The MSDS need not expressly forbid implantation in humans for Dr. Rosenzweig to use its statements about strong oxidizers—which he explains are readily found in the vagina—to support his concerns about mesh use in the vagina. To the extent Ethicon disagrees with Dr. Rosenzweig’s conclusion, Ethicon’s objections are better suited for cross-examination. Ethicon’s Motion on this point is **DENIED**.

Ethicon also argues that Dr. Rosenzweig is unqualified to offer opinions based

on the MSDS because Dr. Rosenzweig does not know how the MSDS was prepared. I disagree. A urogynecologist does not need to be an expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body. Accordingly, Ethicon's Motion is **DENIED** on this point.

e. Complications

Ethicon moves for the exclusion of Dr. Rosenzweig's opinions relating to his allegations that TVT causes cytotoxicity and that Ethicon should have warned physicians of that fact. Additionally, Ethicon argues that Dr. Rosenzweig is not qualified to offer opinions regarding the adequacy of Ethicon's testing regarding cytotoxicity.

The plaintiffs point out that this court previously ruled on this issue in *Huskey*, 29 F. Supp. 3d 691, and the court permitted Dr. Rosenzweig's opinions regarding cytotoxicity. The court's former determination was based on Dr. Rosenzweig's extensive interaction with patients exhibiting complications, surgeries that he has performed, and internal Ethicon studies and documentation showing TVT-O could cause cytotoxicity. *Huskey*, 29 F. Supp. 3d at 705. Dr. Rosenzweig's qualifications are the same in this case. To the extent that Ethicon believes cytotoxicity is not clinically significant, Ethicon may cross-examine Dr. Rosenzweig on that issue. Accordingly, Ethicon's Motion regarding Dr. Rosenzweig's opinions relating to cytotoxicity is **DENIED**.

However, I **FIND** that Dr. Rosenzweig is not qualified to opine that Ethicon's testing was insufficient. There is no indication that Dr. Rosenzweig has any

experience or knowledge on the appropriate testing a medical device manufacturer should undertake. Therefore, Dr. Rosenzweig's testimony that Ethicon failed to appropriately test for cytotoxicity is **EXCLUDED**.

Ethicon next argues that Dr. Rosenzweig's opinion that the shorter length of laser-cut mesh in the TVT Abbrevio leads to more complications should be excluded as unreliable. Dr. Rosenzweig does not cite to any study or personal experience to support his opinion, but he instead cited to an internal Ethicon document that does not support his opinion. Dr. Rosenzweig simply provides no reliable methodology for his opinions regarding laser-cut mesh. These opinions are **EXCLUDED**.

f. Design Process

Ethicon claims Dr. Rosenzweig is not qualified to offer what it characterizes as design opinions. But they do not explain or identify design opinions with sufficient specificity. This most recent wave of *Daubert* motions in this MDL is plagued with some confusion about what constitutes a design opinion. So some clarification is necessary before proceeding.

At first glance, it seems Ethicon wants to prevent Dr. Rosenzweig from providing any opinions that even mention the word "design." But the mere utterance of a single word is not some incantation that transforms an opinion about one thing into something else.

A close, contextual reading of the transvaginal mesh cases where this issue has been raised before reveals the heart of Ethicon's objections. In this motion—and several others—the plaintiffs argue that the expert at issue lacks the particularized

skill, knowledge, experience, education, or training that is necessary to provide opinions about the process of designing a product. Opinions of this sort include, for example, opinions about pre-marketing product testing and product development.

Suffice it to say, an expert opining on these matters must possess skills, knowledge, experience, education, or training particularly relevant to the processes at issue. *See, e.g., Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 550 (S.D. W. Va. 2014) (finding expert who “participated in the development of mesh products” qualified to discuss design procedure). Experience as a practicing urogynecologist or urologist alone does not translate into experience with or knowledge about the process of designing a product.

Ethicon claims Dr. Rosenzweig is not qualified to opine on the design of the relevant mesh products because he does not have any experience with biomaterials or polymer chemistry and because he has not conducted comparative mesh studies. But Dr. Rosenzweig is familiar with the design of surgical products. For example, he has invented a catheter device. In short, this experience combined with surgical experiences makes Dr. Rosenzweig is qualified to provide opinions of this sort.

Furthermore, contrary to Ethicon’s contentions, Dr. Rosenzweig has a reliable basis for his design opinions. He considered more than internal corporate documents in arriving at his opinion on the design of the relevant products; he relied on his experience and relevant scientific literature. His detailed examination of the literature in light of his firsthand experience with mesh devices satisfies the

reliability requirements of *Daubert*. Accordingly, Ethicon's Motion is **DENIED** on this very limited issue.

g. Marketing

Ethicon seeks to exclude Dr. Rosenzweig's expert testimony about whether its products were less effective or less safe for certain patient populations. In the past, I have excluded this testimony because "it is not helpful to the jury to have Dr. Rosenzweig read a document explaining what the inventor of the [product] thought about this. The jury is capable of reading that document itself." *Edwards v. Ethicon, Inc.*, 2:12-cv-9972, 2014 WL 3361923, at *10 (S.D. W. Va. July 8, 2014). I see no reason—nor have I been given one—to depart from this conclusion. Accordingly, Dr. Rosenzweig's expert testimony on this matter is **EXCLUDED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913,

921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon’s compliance with design control and risk management standards. Some of this testimony involves the FDA’s quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and

international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at

a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury’s fact-finding function by allowing testimony of this type, and I do the same here. *E.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit

for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

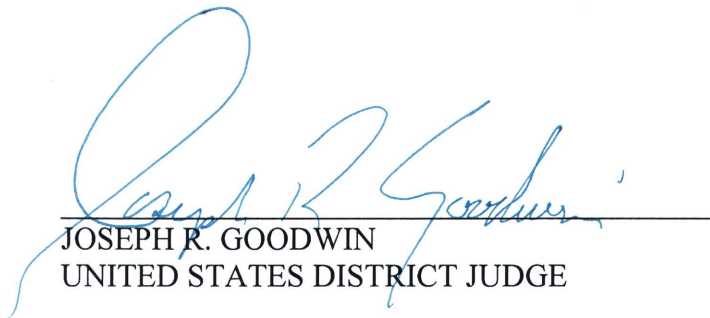
Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude Certain Opinions of Bruce Rosenzweig, M.D. [ECF No. 2047].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 26, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**EXHIBIT A TO MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DR.
BRUCE ROSENZWEIG**

ALL CASES PERTINENT TO MOTION

1. *Marie Banks Smith v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01318 (TVT);
2. *Bonnie Blake, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00995 (TVT);
3. *Karen Bollinger v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01215 (TVT);
4. *Denise Burkhart v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01023 (TVT);
5. *Fran Denise Collins v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00931 (TVT-O);
6. *Patricia Conti v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00516 (TVT);
7. *Carol Jean Dimock v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00401 (Prolift & TVT-O);
8. *Dennis W. Dixon, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01081 (Gynemesh PS);
9. *Karen Forester v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00486 (TVT-O);
10. *Pamela Free v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00423 (TVT);
11. *Susan Guinn v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01121 (TVT-O);
12. *Mary Hendrix, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00595 (TVT);
13. *Rocio Herrera-Nevarez v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01294 (TVT-O);
14. *Jeanie Holmes v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01206 (TVT-O);

15. *Myndal Johnson v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00498 (TVT);
16. *Wilma Johnson v. Ethicon, Inc., et al.*, Civil Action No. 2:112-cv-00809 (Gynemesh PS & TVT);
17. *Holly Jones, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00443 (TVT);
18. *Cheryl Lankston v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00755 (TVT-Secur);
19. *JoAnn Lehman v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00517 (TVT-O);
20. *Heather Long v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01275 (TVT);
21. *Penny Rhynehart v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01119 (Prolift Total & TVT-O);
22. *Brenda Riddell, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00547 (Prolift Anterior & TVT-O);
23. *Patricia Ruiz v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01021 (TVT-Secur);
24. *Debra Schnering, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01071 (TVT);
25. *Donna Shepherd v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00967 (TVT-Secur);
26. *Cherise Springer, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00997 (TVT-O);
27. *Margaret Stubblefield v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00842 (Gynemesh PS);
28. *Kimberly Thomas v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00499 (Prosima Anterior & TVT-O);
29. *Mary Thurston v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00505 (TVT);
30. *Barbara J. Vignos-Ware, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00761 (Prosima Anterior & TVT-O);
31. *Cathy Warlick, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00276 (Prolene Soft Mesh, Prosima Combined & Gynemesh PS);
32. *Judy G. Williams v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00657 (Prolift Posterior & TVT-O);
33. *Nancy Williams v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00511 (Prolift Total & TVT-O);
34. *Christine Wiltgen, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01216 (TVT);

35. *Sandra Wolfe v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00335 (Prolift Total & TVT-O); and

36. *Donna Zoltowski v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00811 (Prolift Total & TVT-O).

**Defendants reserve the right to supplement this list should any other plaintiff be allowed to designate Dr. Rosenzweig as a general causation expert in MDL Wave 1.

Exhibit C

Index of Relevant Pleadings related to Bruce Rosenzweig, M.D.

Judge Goodwin instituted a series of Waves in MDL 2327 wherein he identified hundreds of cases per Wave subject to discovery and motion practice deadlines. As part of the Wave process, Judge Goodwin required parties to file one general causation *Daubert* motion per expert per Wave in the main MDL, rather than in each individual Wave case. Parties were required to identify the cases in each Wave to which a particular *Daubert* motion applied. The court has identified below, the relevant *Daubert* pleadings filed in each Wave (and in many cases ultimately adopted in subsequent Waves) for the court receiving this case on remand or transfer.

Wave 1	Date	WVSD ECF No.
Motion	4/21/16	2047
Memorandum	4/21/16	2049
Response	5/9/16	2163
Reply	5/16/16	2241
Mem Op & Ord	8/26/16	2668

Wave 2	Date	WVSD ECF No	Comment
Motion	7/21/16	2439	Adopts ECF No. 2047
Memorandum	7/21/16	2439	Adopts ECF No. 2049
Response	8/8/16	2528	Adopts ECF No. 2163
Reply	8/18/16	2622	Adopts ECF No. 2241
Mem Op & Ord	3/29/17	3532	Adopts ECF No. 2668

Wave 3	Date	WVSD ECF No	Comment
Motion	9/19/16	2817	Does not adopt
Memorandum	9/19/16	2818	Does not adopt
Response	10/11/16	2931	Does not adopt
Reply	10/20/16	3024	Does not adopt